IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

G.D. SEARLE LLC and PFIZER ASIA PACIFIC PTE. LTD.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 13-cv-121
LUPIN PHARMACEUTICALS, INC., TEVA PHARMACEUTICALS USA, INC., MYLAN PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., APOTEX, INC. and APOTEX CORP.,	)	
Defendants.	)	

WATSON LABORATORIES, INC.'S, LUPIN PHARMACEUTICALS, INC.'S, APOTEX INC.'S AND APOTEX CORP.'S MEMORANDUM IN SUPPORT OF THE JOINT MOTION FOR SUMMARY JUDGMENT OF INVALIDITY OF U.S. PATENT NO. RE 44,048

The time has come for patients in need of pain relief to have access to a less expensive but equally potent alternative. Pfizer has had a monopoly on the pain medication celecoxib, which it sells as Celebrex®, for long enough. Since 2005, Pfizer has earned more than $16 *billion* dollars on Celebrex® in the United States market alone. Pfizer enjoyed its monopoly and profits largely due to the '165 patent, directed to compositions of celecoxib, which expires on November 30, 2013. Realizing that legitimate competition would follow the expiration of the '165 patent, Pfizer attempted to extend its monopoly to June 2, 2015 by asserting a related '068 patent, directed to *methods of using* celecoxib. The United States Court of Appeals for the Federal Circuit rejected Pfizer's attempt, finding the asserted claims of the '068 patent invalid for double patenting because it was not patentably distinct from Pfizer's '165 patent.

Pfizer's defeat before the Federal Circuit did not end its quest to prevent legitimate competition, however. Pfizer returned to the Patent Office and sought to "reissue" the invalidated '068 patent as a "divisional" patent application. Initially the Patent Office rejected Pfizer's attempts, recognizing that failure to file a divisional is not correctable via reissue. Undeterred, Pfizer tried a different approach, pretending this time that the previously asserted '068 patent's claims were "indefinite" for reasons that had nothing to do with whether the patent was a divisional. The Patent Office, in error, allowed the "indefinite" '068 patent to reissue as the RE'048 patent—the patent at issue in this case.

If allowed to stand, this new version of the '068 patent gives Pfizer another 18 months of patent protection, an extended monopoly that it simply does not deserve and to which it is not entitled. As a matter of law, nothing Pfizer did during the reissue prosecution changes the fact that the RE'048 patent, like the '068 patent before it, did not issue from a divisional application. As a matter of law, the RE '048 patent is not valid.

I. STATEMENT OF UNDISPUTED FACTS.

As explained, below, Pfizer continues to make-believe that the RE'048 patent is valid because it now calls the RE'048 patent a "divisional." In reality, the reissued RE'048 patent is different from the invalid '068 patent in name only.

A. Overview of patent procedure.

1. Examination of a U.S. patent application begins when a patent application is filed with the United State Patent and Trademark Office ("PTO"). There are three types of U.S. patent applications: (1) a regular ("nonprovisional") application filed under 35 U.S.C. § 111(a); (2) a provisional application filed under 35 U.S.C. § 111(b); and (3) a national stage application under

the Patent Cooperation Treaty ("PCT") filed under 35 U.S.C. § 371. 35 U.S.C. § 111; 35 U.S.C. § 371; Manual of Patent Examining Procedure ("MPEP") § 1893 (8th ed., Rev. 9, 2012).

2. An applicant has the option of "continuing" its prosecution in later applications. There are three types of "continuing" applications: a continuation application (which must not contain new matter), a continuation-in-part application (which can contain new matter), and a divisional application (which is directed to a subset of original matter). *See Transco v. Performance Contracting*, 38 F.3d 551, 555-56 (Fed. Cir. 1994); MPEP § 201. All continuing applications must be filed while the original application is pending, sometimes referred to as a "copendency" requirement. MPEP § 201.06; 35 U.S.C. § 120.

3. "Obviousness-type double patenting is a judicially created doctrine that 'prohibit[s] a party from obtaining an extension of the right to exclude through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent.'" *Pfizer v. Teva Pharms. USA,* 518 F.3d 1353, 1363 (Fed. Cir. 2008) (citations omitted).

4. An applicant may avoid an obviousness-type double patenting rejection by filing a terminal disclaimer, which is a statement that disclaims some portion of the term of a patent to be granted such that a patent's term will not improperly extend beyond an earlier patent's term. 35 U.S.C. § 253; 37 C.F.R. § 1.321(b) & (c).

5. Because a patent application should not include multiple distinct inventions, the PTO can issue a "restriction requirement" requiring an applicant to elect a single claimed invention for examination. 35 U.S.C. § 121. If a divisional application is filed in response to a PTO restriction requirement, it cannot be rejected for obviousness-type double patenting based on patents that issue from the parent application or divisionals of the parent application. 35 U.S.C. § 121. For this "safe harbor" to apply, there must be "consonance," which means "the applicant must

maintain the line of demarcation between the independent and distinct inventions that prompted the restriction requirement." *Pfizer,* 518 F.3d at 1359. Restriction requirements do not carry over to later continuations. MPEP § 804.01.

6. An applicant may obtain reissue of a patent that is "through error, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim . . . ." 35 U.S.C. § 251.

B. Prosecution of the '068 patent.

7. U.S. Patent Application No. 08/160,594 ("the original '594 application") was filed on November 30, 1993.[1] The RE'048 patent, as well as several other patents, claims priority to the original '594 application. A recitation of the undisputed prosecution history of the relevant applications follows. For the Court's assistance, a diagram (or "family tree") of this history is attached to the Sorenson Declaration as Exhibit 1.[2]

1. The original '594 application.

8. On July 12, 1994, the examiner issued a restriction requirement under § 121 of the claims of the original '594 application to three independent groups of invention: claims 1-20 drawn to compounds (including celecoxib); claims 21-26 drawn to compositions containing those compounds; and claims 27-37 drawn to methods of use of those compounds.[3] In response, the applicant elected to prosecute the compound claims.[4]

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[1] Sorenson Dec. Ex. 2 at PFZCEDV_1287107.
[2] John Doll, the former Commissioner of the United States Patent and Trademark Office, submitted an expert report that is consistent with Defendants' position set forth in this brief. *See* Sorenson Dec. Ex. 17, October 11, 2013 Initial Expert Report of John Doll, at 30.
[3] Sorenson Dec. Ex. 2 at PFZCEDV_1287272-75; *id.* Ex. 3, Pfizer's November 7, 2013 Responses to Watson's Requests for Admission ("RFA") 21.
[4] Sorenson Dec. Ex. 2 at PFZCEDV_1287291-92; *id.* Ex. 3 at RFA 22.

9. The '594 application issued as U.S. Patent No. 5,466,823 ("the '823 patent"), directed to compound claims, on November 14, 1995.[5] The '823 patent expires on November 30, 2013.[6]

2. The continuation-in-part '629 application.

10. U.S. Patent Application No. 08/223,629 ("the continuation-in-part '629 application") was filed on April 6, 1994, as a continuation-in-part of the original '594 application.[7] The continuation-in-part '629 application was not filed in response to the July 12, 1994 restriction requirement; it was filed before the restriction requirement issued.[8] In fact, the continuation-in-part '629 application was not filed in response to any restriction requirement.

11. The continuation-in-part '629 application included compound, composition, and method claims, including new subject matter (referred to as "new matter") not disclosed or claimed in the original '594 application.[9]

12. The continuation-in-part '629 application issued as U.S. Patent No. 5,521,207 ("the '207 patent"), directed to compound, composition, and method claims, on May 28, 1996.[10]

3. The divisional '059 application.

13. As a result of the restriction requirement in the original '594 application, on June 1, 1995, U.S. Patent Application No. 08/457,059 ("the divisional '059 application") was filed as a divisional of the original '594 application.[11] The applicant specifically asserted that the '059

[5] Sorenson Dec. Ex. 4 at PFZCEDV_0757649; *id.* Ex. 3 at RFA 24.
[6] Sorenson Dec. Ex. 3 at RFA 25. Due to ancillary FDA issues, some of the patents have additional terms of exclusivity.
[7] Sorenson Dec. Ex. 5 at PFZCEDV_1312769; *id.* Ex. 3 at RFA 31, 33.
[8] Sorenson Dec. Ex. 2 at PFZCEDV_1287272-75; *id.* Ex. 3 at RFA 28, 35.
[9] Sorenson Dec. Ex. 5 at PFZCEDV_1312861-91; *id.* Ex. 3 at RFA 32; *Id.* Ex. 6 at ROG 2.
[10] Sorenson Dec. Ex. 7 at PFZCEDV_1193581; *id.* Ex. 3 at RFA 36.
[11] Sorenson Dec. Ex. 8 at PFZCEDV_1287644; *id.* Ex. 3 at RFA 23, 26.

application was a divisional of the original '594 application.[12] The applicant elected to prosecute composition claims in the divisional '059 application.[13]

14. The divisional '059 application issued as U.S. Patent No. 5,563,165 ("the '165 patent"), claiming compositions, on October 8, 1996.[14] The '165 patent expires on November 30, 2013.[15]

4. The PCT '720 application.

15. International Patent Application No. PCT/US94/12720 ("the PCT '720 application") was filed on November 14, 1994, as an international filing claiming benefit to the continuation-in-part '629 application and the original '594 application.[16] The PCT '720 application included compound, composition, and method of use claims, including new matter not contained in the original '594 application or the continuation-in-part '629 application.[17]

16. The PCT '720 application was not filed as a divisional of the original '594 application.[18]

17. The PCT '720 application was not filed in response to a restriction requirement in the original '594 application, or any other application.

18. Numerous foreign patents—including claims for compounds, compositions, and methods beyond those disclosed in the '594 application—claim priority to the PCT '720 application.[19]

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[12] Sorenson Dec. Ex. 8 at PFZCEDV_1287822.
[13] Sorenson Dec. Ex. 8 at PFZCEDV_1287822, 1287784-809, 1287827-45.
[14] Sorenson Dec. Ex. 9 at PFZCEDV_0757677.
[15] Sorenson Dec. Ex. 3 at RFA 27.
[16] Sorenson Dec. Ex. 12 at PFZCEDV_1223912; *id.* Ex. 11 at PFC01601966, PFC01501500; *Id.* Ex. 3 at RFA 37, 39-40.
[17] *Id.* Ex. 12 at PFZCEDV_1224097-187; *id.* Ex. 3 at RFA 38, 42; *id.* Ex. 6 at ROG 1.
[18] Sorenson Dec. Ex. 11 at PFC01601966; *id.* Ex. 3 at RFA 28, 30, 43-44.
[19] The following foreign patents claim priority to the PCT '720 application: AU 690609 B2, CA 2177576 C, CA 2276945 C, CN 100379727 C, CN 1061036 C, CN 1127484 C, CN 1134418 C, CN 1268614 C, CY 2237 B1, CZ 294630 B6, EP 731795 B1, EP 922697 B1, EP 923933 B1, EP 924201 B1, FI 115053 B1, HU 223824 B1, HK 1021935, HK 1013649, JP 03025017 B2, JP 03445762 B2, JP 03921451 B2, KR 229343 B1, KR 261669 B1, KR 263817 B1, NO 306460 B1, MX 200516 B, MX 214685, MX 218094, MX 261375, PL 180717 B1, RO 118291 B1, RO 122672 B1, RU 2139281 C1, TW 418193 B, TW 467900 B. *See also* Sorenson Dec. RFA 48, 50.

5. The national stage '113 application.

19. U.S. Patent Application No. 08/648,113 ("the national stage '113 application") was filed with the PTO on May 21, 1996 as a § 371 application (national stage application) from the PCT '720 application.[20] The applicant asserted that "This is an application under 35 USC §371 of International Application PCT/US94/12720, with an international filing date of November 14, 1994, which is a continuation-in-part of U.S. Patent Application Serial No. 08/223,629, filed April 6, 1994, now issued as U.S. Patent No. 5,521,207, which is a continuation-in-part of U.S. Patent Application Serial No. 08/160,594, filed November 30, 1993, now issued as U.S. Patent No. 5,466,823."[21]

20. As filed, the national stage '113 application included compound, composition, and method of use claims, including new matter that was not in the original '594 application.[22]

21. The national stage '113 application was not filed as a divisional of the original '594 application.[23]

22. There is no reference in the national stage '113 application prosecution to the July 12 restriction requirement from the original '594 application.

23. During prosecution of the national stage '113 application, the examiner issued a "lack of unity/restriction requirement between compounds, pharmaceutical compositions and methods of use".[24] In response, the applicant elected to prosecute method claims, and cancelled all of the remaining claims.[25] On September 6, 1996, the claims were allowed.[26] As allowed, the method

[20] Sorenson Dec. Ex. 10 at PFZCEDV_1286412, 1286742, 1287016-17. The application was complete on September 9, 1996. *Id.* Ex. 10 at PFZCEDV_1287016.
[21] Sorenson Dec. Ex. 10 at PFZCEDV_1287020, PFZCEDV_1286412; *id.* Ex. 3 at RFA 55.
[22] Sorenson Dec. Ex. 10 at PFZCEDV_1286657-77; *id.* Ex. 3 at RFA 54; *id.* Ex. 6 at ROG 3.
[23] Sorenson Dec. Ex. 3 at RFA 59.
[24] Sorenson Dec. Ex. 10 at PFZCEDV_1287049.
[25] Sorenson Dec. Ex. 10 at PFZCEDV_1287030-49.

claims of the national stage '113 application included subject matter from the continuation-in-part '629 application and the original '594 application.[27]

24. The claims as allowed in the national stage '113 application were not limited to methods originally claimed in the '594 application.[28]

25. On September 30, 1997, after the claims of the national stage '113 application were allowed and the issue fee paid, the applicant filed a petition to amend before patent issuance.[29] The applicant asserted that it had amended the claims to "remove the subject matter allowed in U.S. Patent No. 5,521,207," which issued from the continuation-in-part '629 application.[30]

26. The national stage '113 application issued as U.S. Patent No. 5,760,068 ("the '068 patent"), directed to method claims, on June 2, 1998.[31]

27. Because the '113 application was filed as a § 371 national stage application of a PCT application filed prior to June 8, 1995,[32] the '068 patent expires on June 2, 2015 (17 years from its June 2, 1998 issue date), 18 months later than the November 30, 2013 expiration dates of the related '165 and '823 patents.[33]

28. If the '068 patent expired 20 years from the date of the earliest application it claims a benefit to, it would expire on November 30, 2013 like the related '165 and '823 patents.

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[26] Sorenson Dec. Ex. 10 at PFZCEDV_1287051.
[27] *See* Sorenson Dec. Ex. 10 at PFZCEDV_1287069.
[28] *See* Sorenson Dec. Ex. 10 at PFZCEDV_1287069.
[29] Sorenson Dec. Ex. 10 at PFZCEDV_1287070.
[30] Sorenson Dec. Ex. 10 at PFZCEDV_1287069.
[31] Sorenson Dec. Ex. 13 at PFZCEDV_0757706, 757755-60; *id.* Ex. 3 at RFA 63.
[32] As discussed in § II.B.3, this date is important for calculating patent terms. MPEP § 2701.
[33] MPEP § 2701; Sorenson Dec. Ex. 3 at RFA 64.

C. The Federal Circuit found the '068 patent invalid.

29. In 2004, Pfizer filed a patent infringement suit against Teva in the District of New Jersey. *Pfizer Inc. v. Teva Pharms. U.S.A., Inc.*, 04-754 (D.N.J.). Pfizer accused Teva of infringing claims 1-4 and 11-17 of the '068 patent, asserting that those claims were valid.[34]

30. The Federal Circuit held that the asserted claims of the '068 patent directed to methods of using compositions of celecoxib were invalid based on obviousness-type double patenting in view of the '165 patent, which claimed the composition of celecoxib. *Pfizer,* 518 F.3d at 1363. The court explained that "[t]he claims at issue of the '068 patent merely recite methods of administering a 'therapeutically-effective amount' of the compositions found in claim 5 of the '165 patent." *Id.* As the court explained, "the '068 patent merely claims a particular use described in the '165 patent of the claimed compositions of the '165 patent." *Id.* The court rejected Pfizer's arguments that claims directed to the particular disorders of arthritis, pain, and fever, should be considered separately, stating "[w]e find that these recitations do not claim non-obvious subject matter, since claim 5 of the '165 patent generally claims compounds, which the specification indicates are used to treat 'inflammation-related disorders.'" *Id.* at n.9. As the court explained, "It would shock one's sense of justice if an inventor could receive a patent upon a composition of matter, setting out at length in the specification the useful purposes of such composition, manufacture and sell it to the public, and then prevent the public from making any beneficial use of such product by securing patents upon each of the uses to which it may be adapted." *Id.* at 1363 n.8 (citation omitted).

31. The court held that the § 121 safe harbor did not apply because the '068 patent applicant did not file a divisional in response to a restriction requirement. *Id.* at 1358-59.

[34] Sorenson Dec. Ex. 3 at RFA 75.

32. Thus, the Federal Circuit held that Pfizer's monopoly on celecoxib would end on November 30, 2013, with the expiration of the '823 and '165 patents. Because the '068 patent claimed the same subject matter as the '165 patent, it could not extend Pfizer's monopoly to June 2, 2015.

D. Prosecution of the reissue RE'048 patent.

33. After claims of the '068 patent were invalidated, Pfizer sought reissue of the '068 patent. Reissue Application No. 12/205,319 ("the reissue application") was filed on September 5, 2008.[35]

34. The reissue application was not filed in response to a restriction requirement.

35. Pfizer represented it was amending the claims and specification "so that the '113 Application from which the '068 Patent issued qualifies as divisional application in compliance with the recent Federal Circuit opinion."[36] The PTO rejected this because "Failure to 'timely' file divisional application prior to issuance of original patent is not correctable in reissue."[37]

36. Pfizer did not give up, and again requested reissue for similar reasons,[38] which the PTO rejected again because "failure to 'timely' file a divisional application prior to issuance of original patent is not correctable in reissue".[39]

37. Pfizer then asserted (for the first time) that it had claimed, in its original prosecution, "more or less than [it] had the right to claim in the patent."[40] Specifically, Pfizer asserted in its

[35] Sorenson Dec. Ex. 14 at PFH_0000001, 37-38.
[36] Sorenson Dec. Ex. 14 at PFH_0000012.
[37] Sorenson Dec. Ex. 14 at PFH_0012327-29.
[38] Sorenson Dec. Ex. 14 at PFH_0019627.
[39] Sorenson Dec. Ex. 14 at PFH_0025411.
[40] Sorenson Dec. Ex. 14 at PFH_0025444.

reissue oath[41] that "[o]ne such error is that, as detailed below, claim 1, col. 98, lines 31-46 includes several substituents that make indefinite the meaning of the claim. . . . Claim 2 also has errors correctable by reissue. For example, Claim 2 does not further limit claim 1 and accordingly is an improper dependent claim. . . ."[42]

38. In response to further rejections, Pfizer argued that the reissue oath was proper because "Applicants have identified multiple errors based on indefinite claim terms and failure to include narrower claims in the original patent, each of which independently support Applicants' reissue application, each of which is recognized as an appropriate basis for reissue . . . ."[43]

39. The PTO then allowed the reissue application, and U.S. Patent No. RE44,048 ("the RE'048 patent") issued on March 5, 2013.[44]

40. Pfizer claims that the RE'048 patent expires on June 2, 2015.[45]

41. Pfizer takes the position that four patents cover celecoxib, which Pfizer sells as Celebrex®: the '823 patent, the '165 patent, the RE'048 patent, and the '068 patent.[46]

42. The RE'048 patent is directed to the same subject matter as the '165 patent.[47]

43. Pfizer admits that the compounds claimed in the '165 patent are used to treat inflammation-related disorders.[48] Pfizer takes the position that all of the disorders in the method of use claims of the RE'048 patent are inflammation-related disorders.[49]

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[41] A signed and sworn oath that the reissue complies with the reissue statute is required for a reissue patent. 37 C.F.R. §§ 1.172, 1.175; MPEP § 1414.
[42] Sorenson Dec. Ex. 14 at PFH_0025433-37.
[43] Sorenson Dec. Ex. 14 at PFH_0036741.
[44] Sorenson Dec. Ex. 14 at PFH_0039421; *id.* Ex. 15 at PFZCEDV_0756387.
[45] Sorenson Dec. Ex. 16 at WAT-CEL-00021014-16; *id.* Ex. 3 at RFA 68.
[46] Sorenson Dec. Ex. 16 at WAT-CEL-00021014-16; *id.* Ex. 3 at RFA 73.
[47] Sorenson Dec. Ex. 3 at RFA 2.
[48] Sorenson Dec. Ex. 3 at RFA 3-13, 15, 16.
[49] Sorenson Dec. Ex. 3 at RFA 3-16.

II. ARGUMENT: There are no disputed fact issues—the RE'048 patent is invalid as a matter of law.

Summary judgment should be granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *Celotex v. Catrett*, 477 U.S. 317, 322-23 (1986). Summary judgment is as appropriate in patent cases as any other case. *Barmag v. Murata Machinery*, 731 F.2d 831, 835 (Fed. Cir. 1984). Whether an applicant satisfies the statutory requirements of 35 U.S.C. § 251 is a question of law. *In re Serenkin*, 479 F.3d 1359, 1361 (Fed. Cir. 2007). Whether a patent is invalid due to double patenting is also an issue of law. *Pfizer,* 518 F.3d at 1363.

Pfizer's entire case hinges on whether the RE'048 patent can claim priority back to the '594 application *as a divisional*. There are no disputed issues of fact that prevent the fair and immediate adjudication of Pfizer's claims as a matter of law because failure to file a divisional is not correctable as a matter of law and the RE'048 patent did not issue from a divisional.

The RE'048 patent is invalid for failing to meet the reissue requirements of 35 U.S.C. § 251. Failure to file a divisional is not correctable via reissue and intentional decisions are not correctable via reissue. On this basis alone, the Court should conclude as a matter of law that the RE'048 patent is invalid for failing to comply with the reissue requirements.

In addition, the RE'048 patent did not issue from a divisional of the original '594 application. The national stage '113 application (from which the '068 patent and subsequent RE'048 patent issued) was never co-pending with the original '594 application; the *only* way it can claim priority to that application is through the PCT '720 application, which means it must be a § 371 national stage application and not a divisional application. The reissue application did not and could not change that lineage. Thus, the RE'048 patent is invalid for obviousness-type double patenting for the same reason the '068 patent was found invalid by the Federal Circuit.

The § 121 safe harbor, which excuses divisional applications filed in response to a restriction requirement from being rejected due to obviousness-type double patenting rejections, does not apply because the national stage '113 application is not a divisional of the original '594 application, and nothing done during reissue prosecution changes this historic fact. Like the '068 patent, the RE'048 patent merely claims a particular use described in the '165 patent of the compositions claimed in the '165 patent, and thus it is invalid for double patenting.

A. The RE'048 patent is invalid under § 251 for failing to meet the reissue requirements.

An applicant may obtain reissue "[w]henever any patent is, through error, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent. . . ." 35 U.S.C. § 251. "The reissue statute was not enacted as a panacea for all patent prosecution problems, nor as a grant to the patentee of a second opportunity to prosecute de novo his original application." *In re Weiler*, 790 F.2d 1576, 1582 (Fed. Cir. 1986). If a reissue patent fails to meet the reissue requirements, it is invalid. *N. Am. Container, Inc. v. Plastipak Packaging, Inc.*, 415 F.3d 1335, 1349 (Fed. Cir. 2005).

There are two separate reasons why the RE'048 patent is invalid for failing to meet the reissue requirements. First, failure to file a divisional is *not* correctable via reissue as a matter of law. Therefore, Pfizer cannot "cure" its failure to file a divisional with reissue. Second, intentional acts are not correctable via reissue. Yet that is exactly what Pfizer is attempting to do. Indeed, there is no genuine issue of material fact underlying the conclusion that the following decisions were intentional acts: (1) filing the '629 application as a continuation-in-part; (2) filing the PCT '720 application as the international filing of the continuation-in-part '629 application; (3) filing the '113 application as a § 371 national stage application of the PCT '720 application;

and (4) choosing not to file a divisional from the original '594 application drawn to method claims. Because intentional acts are not correctable via reissue, the RE'048 patent is invalid.

1. Failure to file a divisional is not correctable via reissue.

"[T]he failure to file a divisional application, regardless of the propriety of the underlying restriction requirement, is not an error correctable by reissue under 35 U.S.C. § 251." *In re Watkinson*, 900 F.2d 230, 231 (Fed. Cir. 1990); *see also In re Doyle*, 293 F.3d 1355, 1358 (Fed. Cir. 2002) (same); *In re Weiler*, 790 F.2d 1576, 1582 (Fed. Cir. 1986) ("By acquiescing in the examiner's restriction requirement, and failing to file divisional applications on the subject matter of non-elected claims, Weiler foreclosed (because that was not error) his right to claim that subject matter."); *In re Orita*, 550 F.2d 1277, 1281 (CCPA 1977) ("Should appellants prevail [in obtaining reissue claims] the copendency requirement [of Section 120] would become meaningless, for should an applicant fail to file a divisional application while maintaining copendency as required by section 120, he could simply revert to Section 251 order to cure his mistake. Section 251 is not a panacea designed to cure every mistake which might be committed by an applicant or his attorney, and the case at bar exemplifies a mistake which this section cannot cure.").

There is no question that Pfizer pursued the RE'048 patent to correct its failure to file the '113 application as a divisional. It was that failure to file that led to the invalidity of the '068 patent. Throughout the prosecution of the reissue application, the PTO repeatedly took the position that failure to file a divisional was not correctable via reissue, and the examiner promptly and correctly rejected Pfizer's attempts to undo its deliberate choice not to file a divisional. It was not until Pfizer filed a supplemental reissue declaration that "identifies more

than one error in claims 1, 2, 3, 7, 8, and 12"[50] of the '068 patent—unrelated to the question of whether a reissue can be used to correct the failure to file a divisional—that the PTO accepted the new reissue declaration and ultimately incorrectly allowed the RE'048 patent.[51]

Pfizer believes that it was able to correct its failure to file a divisional because it corrected other alleged "legitimate" errors. This court should reject that notion. Failure to file a divisional is simply not correctable via reissue regardless of how many other errors Pfizer may allegedly find. Case authority makes clear that there are certain errors that are not correctable by reissue. The error here—the decision not to file a divisional application—is one of those errors that cannot be corrected. *See Watkinson*, 900 F.2d at 231. What the law forbids to be done directly cannot be made lawful by doing it indirectly. *See, e.g., Panther Pumps & Equipment Co. v. Hydrocraft, Inc.,* 566 F.2d 8, 18, 1977 (7th Cir. 1977) (quoting *Pepper v. Litton,* 308 U.S. 295, 311 (1939) ("he cannot violate rules of fair play by doing indirectly through the corporation what he could not do directly")). The reissue did not "cure" Pfizer's failure to file a divisional, and the RE'048 patent is invalid for failing to meet the reissue requirements.

2. Intentional acts are not correctable via reissue.

"[T]he deliberate action of an inventor or attorney during prosecution generally fails to qualify as a correctable error under § 251." *Serenkin*, 479 F.3d at 1362. In *Serenkin*, the court considered a situation where "an applicant who intentionally and knowingly surrendered his right to a claim of priority, in exchange for a benefit, and now is unhappy with his choice." *Id.* at 1364. Specifically, during prosecution the applicant made the choice to forgo an earlier filing date in exchange for inclusion of drawings in his PCT application, and later tried to use reissue to obtain the earlier filing date. *Id.* at 1360-61. The court explained that "the act of choosing a later

[50] Sorenson Dec. Ex. 14 at PFH_0025433-37.
[51] Sorenson Dec. Ex. 14 at PFH_0039421.

filing date during prosecution of the PCT application in exchange for inclusion of missing drawings," does not constitute an error that is correctable under § 251. *Id.* at 1362. The court explained, "[t]he distinction is between a genuine error, or mistake, and a deliberate, but subsequently found to be disadvantageous, choice." *Id.* at 1364; *see also In re Mead*, 581 F.2d 251, 257 (CCPA 1978) ("When his attorney made the conscious choice of breaking appellant's chain of copendency by letting the application issue . . . he knew, or should have known, that there could exist intervening references . . . which could defeat patentability of the disclosed but unclaimed subject matter in the original patent. That intentional omission of the appealed subject matter from the original application combined with the plan to claim it in the subsequent application, does not constitute 'error' under § 251 . . . .").

Pfizer has improperly used the reissue process in attempting to avoid the consequences of the deliberate and knowing choice it previously made to file a continuation-in-part application rather than a divisional of the original '594 application directed to methods of use. Indeed, the applicant did not intend to file a divisional when it filed continuation-in-part '629 application, did not intend to file a divisional when it filed the PCT '720 application, and it did not intend to file a divisional when it filed the national stage '113 application. All applications were proper and their benefits—of which there are many[52]—were fully exploited.

That the applicant made a choice not to file a divisional when it filed the PCT '720 and national stage '113 applications is demonstrated by every aspect of their prosecution. For example, the national stage '113 application was identical to and claimed priority to the PCT '720 application, which in-turn claimed priority to the continuation-in-part '629 application that was filed before there was even a restriction requirement in the original '594 application.

[52] As discussed in section II.B.4 below, the applicant's prosecution choices allowed it to obtain a longer patent term.

Furthermore, when it was filed the national stage '113 application included new matter not in the original '594 application, including compound, composition, and method claims. As a result, the national stage '113 application did not contain *only* method claims or *only* claims limited to using the compounds disclosed and claimed in the original '594 application, both of which would be required for a "divisional" filed as the result of a restriction requirement. *See Pfizer,* 518 F.3d at 1359 (requiring consonance). Also, the national stage '113 application was not co-pending with the original '594 application. The national stage '113 application could only claim a relationship to the original '594 application because it was a national stage application of the PCT '720 application. These deliberate decisions simply are not errors, let alone errors correctable through reissue proceedings. Nor has Pfizer ever claimed that any of these choices were accidental, mistakes, or otherwise unintentional, because it cannot. Because an applicant cannot correct an intentional act using the reissue process, the RE'048 patent violates § 251.

This is also not a situation where the applicant of the national stage '113 application just "forgot" to claim priority, and it is easily distinguishable from those cases where a party was allowed to make a forgotten priority claim. *See, e.g.*, *Fontijn v. Okamoto*, 518 F.2d 610, 614 (CCPA 1975) (allowing patentee to use reissue when it failed to notify PTO of earlier-filed copending applications during prosecution of original application). Here the applicant of the national stage '113 application did claim priority to the PCT '720 application, and it did so timely, properly, and correctly. At the time that priority claim was made, it would have been entirely improper for the applicant of the national stage '113 application to claim divisional status, much less divisional status directly to the original '594 application. Nothing was forgotten here. The law does not permit a party to entirely re-cast and re-prosecute its patent application to undo prior deliberate and intentional decisions. *Weiler*, 790 F.2d at 1582; *Serenkin*, 479 F.3d at

1364. Because intentional acts are not correctable via reissue, the RE'048 patent violates the reissue statute § 251 as a matter of law and is invalid. *See N. Am. Container*, 415 F.3d at 1349.

B. The RE'048 patent is invalid for obviousness type double patenting.

The substance of an application controls its priority, not what the patentee calls the application. *See Transco Prods. v. Performance Contracting*, 38 F.3d 551, 556 (Fed. Cir. 1994); *Racing Strollers, Inc. v. Tri Indus., Inc.*, 878 F.2d 1418, 1419 (Fed. Cir. 1989); *see generally Advance Transformer Co. v. Levinson*, 231 U.S.P.Q. 1, 16 (N.D. Ill. 1986); *Reynolds Metals Co. v. Continental Group, Inc.*, 525 F. Supp. 950, 970-71 (N.D. Ill. 1981).

Through the reissue process, Pfizer has declared the RE'048 patent to be both a § 371 national stage application of the PCT '720 application *and* a "divisional" of the original '594 application.[53] However, no such hybrid application exists. Nor would this type of hybrid even be possible, because there is no regulatory mechanism to provide for it. As one example for why this would not be possible, a patent issuing from such a hybrid would have two filing dates and, therefore, two different patent terms. This is because a "divisional" application is given a filing date of the day the application was filed, whereas a § 371 application is awarded its PCT parent's filing date, regardless of when it was filed. A patent with multiple terms would, obviously, be a ridiculous outcome, and a strong case in point for the case law admonition that one must look behind the labels given by the parties.

Looking behind what Pfizer calls it, the RE'048 patent remains the product of a § 371 national stage filing, nothing more and nothing less. And it is because of this true singular status that the claims of the RE'048 patent, like those of its predecessor, are invalid. The RE'048 patent did not issue from a divisional of the original '594 application, and the reissue prosecution did

[53] Sorenson Dec. Ex. 14 at PFH_0000069, PFH_0019616.

not and could not change the national stage '113 application as filed or prosecuted. Again, these historical facts cannot be changed by Pfizer's present-day rhetoric. Nothing Pfizer did or could do during the reissue prosecution changes the fact that the national stage '113 application claims priority to the PCT '720 application, which is an international filing claiming benefit to the continuation-in-part of the '629 application and original '594 application, and thus cannot be a "divisional" of the original '594 application.

1. Section 371 does not provide for divisionals.

Nonprovisional applications are filed under § 111(a), *not* § 371. 35 U.S.C. § 111; 35 U.S.C. § 371; MPEP § 1893. The PTO implemented rules requiring divisional applications to be filed under 37 C.F.R. § 1.53, which relates only to *nonprovisional* applications. 37 C.F.R. § 1.53. As MPEP § 201.06(c) explains, national stage applications under § 371 are *not* filed under 37 CFR § 1.53(b). MPEP § 201.06(c) ("37 CFR 1.53(b) is the section under which all applications are filed EXCEPT: (A) an application resulting from entry of an international application into the national stage under 35 U.S.C. 371. . . .").

There is a mechanism for applicants to use § 111(a) to submit continuing applications of *PCT applications* (not any U.S. application the PCT application may claim priority to), including divisional applications. In such a case, instead of filing § 371 national stage application, the applicant can use a § 111(a) application. The MPEP specifically recognizes "[i]t is possible to file a U.S. national application *under 35 U.S.C. 111(a)* during the pendency (prior to the abandonment) of an international application which designates the United States *without completing the requirements for entering the national stage under 35 U.S.C. 371(c)*." MPEP § 1895 (emphasis added). The MPEP explains that "[b]ecause these continuation applications historically resulted from a need to bypass the requirements of 35 U.S.C. 371, they became

known as 'bypass' applications." *Id.* As the MPEP explains, these § 111(a) applications are considered continuing applications from the *pending PCT application*:

> Rather than submitting national stage application papers under 35 U.S.C. 371, a continuing application (i.e., continuation, C-I-P, or division) under 35 U.S.C. 111(a) of the international (PCT) application may be filed. Pursuant to 35 U.S.C. 365(c), a regular national application filed under 35 U.S.C. 111(a) and 37 CFR 1.53(b) (not under 37 CFR 1.53(d)) may claim benefit of the filing date of an international application which designates the United States.

MPEP § 1895.01; *see also id.* ("An example of an appropriate first sentence of the specification is, for example, 'This is a continuation of International Application PCT/EP2004/000000, with an international filing date of January 5, 2004, now abandoned.'").

There is no authority for any suggestion that a § 371 application can *also* be a divisional application. Nothing in the U.S. Code, Code of Federal Regulations, Manual of Patent Examining Procedure, or any case provides for § 371 national stage applications to be considered divisionals of the PCT applications to which they claim priority. The only authority for divisional applications relates to applications filed under § 111(a).

Thus, Pfizer's suggestion that the national stage '113 application, which was filed under § 371, is a "divisional" is contrary to law. While there was a mechanism for the applicant to file a § 111(a) divisional of the PCT '720 application, the applicant did not pursue that option. Likewise, the applicant could have filed a § 111(a) divisional of the original '549 application, but the applicant did not pursue that option either. Instead, the applicant chose to file the national stage '113 application as a § 371 application. There is no authority that a § 371 application can be considered a "divisional" of the '594 application.

2. The reissue application—like the national stage '113 application—is a § 371 application claiming priority to the PCT '720 application.

A § 111(a) application is not the same as a § 371 application; an application can be one or the other but not both. 37 C.F.R. § 1.9(a)(1) (2008) ("A national application as used in this chapter means a U.S. application for patent which was either filed in the Office under 35 U.S.C. 111, or which entered the national stage from an international application after compliance with 35 U.S.C. 371." (emphasis added)); 35 U.S.C. § 111; 35 U.S.C. § 371; MPEP §§ 1893, 1896.

During reissue prosecution, Pfizer asserted the reissue application "is a 35 U.S.C. § 371 National Stage Application of PCT/US 94/12720 filed Nov. 14, 1994, *and* divisional of U.S Application No. 08/160,594…."[54] Pfizer takes the position that the reissue application—*unlike* the national stage '113 application—is a § 111(a) application such that it can be a divisional of the original '594 application. At the same time, Pfizer takes the position that the reissue application—*like* the national stage '113 application—is a § 371 application such that it can take advantage of the priority claim to the PCT '720 application. This is wrong.

There is no authority to permit an application to be *both* a nonprovisional application filed under 35 U.S.C. 111(a) *and* a national stage application under the PCT filed under § 371. 35 U.S.C. § 111; 35 U.S.C. § 371; 37 CFR 1.53(b); MPEP §§ 1893, 1896. Indeed, the MPEP gives specific instructions to examiners regarding how to determine whether an application is a regular domestic national application filed under 35 U.S.C. 111(a) or a national stage application under the PCT filed under § 371. MPEP § 1893.03(a). Section 1896 of the MPEP also recognizes that the differences between these applications are important:

> The following section describes the differences between a U.S. national application filed under 35 U.S.C. 111(a), including those claiming benefit of a PCT application under 35 U.S.C. 120 (a continuation, division, or a continuation-

[54] Sorenson Dec. Ex. 14 at PFH_0019616 (emphasis added).

> in-part of a PCT application), and a U.S. national stage application (submitted under 35 U.S.C. 371). . . . The differences between a national application filed under 35 U.S.C. 111(a) and a national application submitted under 35 U.S.C. 371 are often subtle, but the differences are important.

The '113 application and the reissue application can be considered a § 111 application or a § 371 application, not both. And a review of the prosecution history demonstrates that the national stage '113 application was a § 371 application, not a domestic national application filed under § 111(a). Since the national stage '113 application was not co-pending with the original '594 application it could not have been (and could never be) a divisional of the original '594 application. The only way the national stage '113 application is connected to the original '594 application is through the PCT '720 application, which is also not a divisional of the original '594 application.

There is nothing about the reissue prosecution that changes those facts. The reissue prosecution cannot "cure" the family relationship. The reissue application—like the national stage '113 application—must be considered a § 371 application.[55] Pfizer concedes this point by taking the position that the RE'048 patent is entitled to the PCT '720 application filing date.[56] In the absence of the PCT '720 application, there is no copendency between the national stage '113 application or the reissue application and the original '594 application. Pfizer cannot ignore the PCT '720 application because, without it, there is no connection between the national stage '113 application or reissue application and the original '594 application. Pfizer's efforts to label the reissue application a § 111 divisional application fail as a matter of law. When the PCT '720 application is properly considered, the national stage '113 application and the reissue application

[55] In reality, the reissue application was not filed under § 111 or § 371; it was filed under § 251. A reissue patent is considered a "continuation" of the original patent. 35 U.S.C. § 252. For purposes of this motion, Defendants will not dispute that the reissue application can be considered the same type of application as the application the original patent issued from.
[56] Sorenson Dec. Ex. 14 at PFH_0000021, 55, 69, 145.

must be § 371 applications. Accordingly, the national stage '113 application is not a divisional of the original '594 application, and Pfizer's representation to the contrary is incorrect.

3. The intervening continuation-in-part '629 application prohibits the national stage '113 application and reissue application from being considered divisionals of the original '594 application.

Even if failure to file a divisional were correctable via reissue—which it is not—and even if an application could be both a national stage application of a PCT application under § 371 and a divisional of a separate application under § 111—which it cannot—the reissue application *still* could not be a divisional of the original '594 application because there are other intervening applications.

The PCT '720 application is not the only thing standing between the national stage '113 application and the original '594 application. The PCT '720 application claims priority to the '629 application as a continuation-in-part, which is a continuation-in-part of the original '594 application. The '113 application is a § 371 national stage filing of the PCT '720 application, and the PCT '720 application is an international filing claiming benefit to the continuation-in-part '629 application. Because the '629 application is a continuation-in-part of the original '594 application, none of the children of continuation-in-part '629 application can be divisionals of the original '594 application. MPEP § 201.06.

The intervening '629 application, which was a continuation-in-part of the original '594 application, and the PCT '720 application clearly prohibit the national stage '113 application and reissue application from being considered divisionals of the '594 application. That is, by virtue of being continuations-in-part, the '629 application, the PCT '720 application, and their progeny claimed new matter not found in the original '594 application, statutorily preventing them from being considered divisional applications that may not have new subject matter.

Pfizer has incorrectly taken the position that the RE'048 patent issued from an application that was a "divisional" of the original '594 application. Applicant's amendments to the disclosure of the '068 patent purporting to cancel all of the subject matter not in the original '594 application during the reissue prosecution did not and could not make the reissue application or the national stage '113 application as filed a "divisional" of the original '594 application. Nothing done during the reissue prosecution can change the fact that RE'048 patent is a descendant of a national stage filing (the national stage '113 application), which claims priority to the continuation-in-part '629 application.

4. Pfizer attempts, unsuccessfully, to retain the benefit of its § 371 filing—a longer patent term—without the corresponding drawbacks—invalidating prior art.

The date a patent expires depends on several factors, including the filing date of the application and the issue date of the patent. For applications filed prior to June 8, 1995, patents expired either 20 years from filing or 17 years from issuance, whichever is later. MPEP § 2701. For applications filed on or after June 8, 1995, the patents issuing from those applications expire twenty years from the filing date of earliest application for which a benefit is claimed, regardless of whether the application for which a benefit is claimed under was filed prior to June 8, 1995. *Id.* "A patent granted on an international application filed before June 8, 1995, and which entered the national stage under 35 U.S.C. 371 before, on or after June 8, 1995, will have a term that is the greater of seventeen years from the date of grant or twenty years from the international filing date or any earlier filing date relied upon under 35 U.S.C. 120, 121 or 365(c)." *Id.*

The national stage '113 application was deposited with the PTO on May 21, 1996.[57] Because the national stage '113 application is a § 371 application, the national stage '113

[57] Sorenson Dec. Ex. 10 at PFZCEDV_1286742, PFZCEDV_1287016-17.

application was awarded the international filing date of the PCT '720 application (November 14, 1994) as its filing date.[58] The filing date of the PCT '720 application can only be the filing date of the national stage '113 application if the latter was filed as a § 371 application. MPEP § 1896. Because the national stage '113 application received the filing date of the PCT '720 application (November 14, 1994), not the date the application papers were actually deposited at the PTO (May 21, 1996), the '068 patent is entitled a patent term of the longer of 17 years from filing or 20 years from the earliest filing date. 35 U.S.C. § 371; MPEP § 2701. Thus, the '068 patent would expire on June 2, 2015. This is later than the '823 and '165 patents, which expire on November 30, 2013.

Had the applicant properly filed a divisional from the original '594 application, the resulting patent would have expired sooner. For applications filed on or after June 8, 1995 (the national stage '113 application was filed on May 21, 1996), the patents issuing from those applications expire twenty years from the filing date of earliest application for which a benefit is claimed. MPEP § 2701. If the national stage '113 application, filed on May 21, 1996, claimed benefit to the original '594 application as a divisional, it would expire 20 years from the filing date of the original '594 application (the earliest U.S. application to which priority is claimed, filed November 30, 1993), which would be November 30, 2013.[59] That is the expiration dates of the '823 and '165 patents, which issued from § 111 applications claiming priority to the original '594 application.

Pfizer made calculated choices during prosecution of the '068 patent. Specifically, Pfizer took advantage of the PCT process to obtain the latest possible expiration date. By choosing to

[58] Sorenson Dec. Ex. 13 at PFZCEDV_00757706.
[59] Had the national stage '113 application been filed prior to June 8, 1995 (instead of on May 21, 1996), it likely would have issued earlier and expired sooner.

file the national stage '113 application as a § 371 application instead of a § 111 application, the applicant obtained the benefit of the PCT '720 filing date, which entitled the applicant to file its application as late as possible and obtain the longest possible patent term. But a downside of that decision was that the resulting patent could be invalid for double patenting, which is what ultimately happened. Pfizer now seeks, through the RE'048 patent, to retain the benefit of its choices without any of the downside. Pfizer wrongly claims that the reissue application can *both* expire on June 2, 2015 as a § 371 application (due to the filing date of the PCT '720 application) *and* avoid an obviousness-type double patenting rejection (i.e. enjoy the benefit of the § 121 "safe harbor") by being a § 111 divisional of the original '594 application. As discussed above, this is incorrect, and this Court should reject Pfizer's attempt to game the system.

Pfizer had options to preserve the validity of the '068 patent. During prosecution of the national stage '113 application, the applicant could have filed a terminal disclaimer to avoid a double patenting rejection so that it would expire on November 30, 2013 along with the '165 patent. 35 U.S.C. § 253; 37 C.F.R. § 1.321(b) & (c). Indeed, during prosecution of the continuation-in-part '629 application, the applicant filed a terminal disclaimer over the original '594 application.[60] But the applicant did not file a terminal disclaimer over the original '594 application during prosecution of the national stage '113 application.[61] Again, Pfizer made a calculated risk to have a longer term on the '068 patent with the possibility that it would be invalidated, which is exactly what happened when the Federal Circuit found the '068 patent invalid in light of the '165 patent.

5. The § 121 safe harbor does not apply because the national stage '113 application and reissue application are not divisionals and were not filed as a result of a restriction requirement.

[60] Sorenson Dec. Ex. 3 at RFA 34.
[61] Sorenson Dec. Ex. 3 at RFA 62.

Under § 121, a divisional filed in response to a restriction requirement issued by the PTO cannot be rejected for obviousness type double patenting based on a patent issuing from the parent application or a divisional from the parent application. 35 U.S.C. § 121. This § 121 "safe harbor" applies *only* to a *divisional* application *filed as a result of* a restriction requirement. *Id.*; *Pfizer,* 518 F.3d at 1362; *see also Amgen v. F. Hoffman-La Roche*, 580 F.3d 1340, 1352 (Fed. Cir. 2009); *Gerber Garment Tech. v. Lectra Sys*., 916 F.2d 683, 687 (Fed. Cir. 1990). Thus, if an applicant files an application without a PTO issued restriction requirement, the examiner or the court can properly issue a double patenting rejection of the claims over the patent of a parent application. MPEP § 804.01 ("[T]he prohibition against double patenting rejections under 35 U.S.C. 121 does not apply . . . [when] [t]he applicant voluntarily files two or more applications without a restriction requirement by the examiner."). In addition, "a restriction requirement in an earlier-filed application *does not carry over* to claims of a continuation application in which the examiner does not reinstate or refer to the restriction requirement in the parent application. Reliance on a patent issued from such a continuation application to reject claims in a later-filed divisional application is not prohibited under 35 U.S.C. 121." MPEP § 804.01 (emphasis added); *Bristol-Myers Squibb v. Pharmachemie*, 361 F.3d 1343, 1348 (Fed. Cir. 2004).

The point of the § 121 "safe harbor" is that courts will not punish patentees who are forced, in response to a PTO restriction requirement, to file a divisional. This rule was not meant to permit patentees like Pfizer to unfairly extend their patent term. As discussed above, the national stage '113 application—and reissue application—are not divisionals of the original '594 application. The § 121 safe harbor does not apply here because it only applies to divisionals.

Even if the national stage '113 application and the reissue application could be considered divisionals of the original '594 application—which they cannot for all of the reasons discussed

above—the § 121 safe harbor still could not apply because the safe harbor only applies to applications filed as a *result* of a restriction requirement. The safe harbor does not apply here because nothing that happened leading up to the filing of the national stage '113 application included *filing* a divisional as a result of a restriction requirement issued by the PTO.

Neither the continuation-in-part '629 application, nor the PCT '720 application, nor the national stage '113 application were *filed* as a *result* of a restriction requirement. The applicant elected to voluntarily add subject matter and file the '629 application as a continuation-in-part of the original '594 application months before any restriction requirement in the original '594 application. Both the national stage '113 application and the PCT '720 application claim priority to the continuation-in-part '629 application, included new matter beyond what is disclosed in the '594 application, and included compound, composition, and method of use claims. They were not *filed* as a *result* of a restriction requirement in the original '594 application, which was based on the necessity to *separate* method, composition, and compound claims. Nor were they limited as filed to the content in the '594 application. Neither the PCT '720 application, nor the continuation-in-part '629 application, nor the national stage '113 application were filed and/or prosecuted with a specific subset of claims as a result of the restriction requirement issued in the original '594 application. The reissue application also was not filed in response to a restriction requirement, and could not change the previous applications as filed. Because the national stage '113 application was not filed as a result of a restriction requirement, there is no safe harbor.

6. The RE'048 patent is invalid for double patenting.

The judicially created doctrine of obviousness type double patenting prohibits a patentee from obtaining a patent on "merely obvious variants of what has been patented" and prevents a patentee from obtaining an extension of patent exclusivity beyond the statutory term. *Gen. Foods*

v. Studiengesellschaft Kohle, 972 F.2d 1272, 1280 (Fed. Cir. 1992) (emphasis omitted); *see also Perricone v. Medicis*, 432 F.3d 1368, 1372 (Fed. Cir. 2005); *Georgia-Pacific v. U.S. Gypsum*, 195 F.3d 1322, 1326 (Fed. Cir. 1999).

As the Federal Circuit previously recognized, "the '068 patent merely claims a particular use described in the '165 patent of the claimed compositions of the '165 patent." *Pfizer*, 518 F.3d at 1363. The same holds true with regard to the RE'048 patent, which Pfizer admits is not patentably distinct from the '165 patent.[62] This lack of patentable distinction is bolstered by Pfizer's admissions that the compounds claimed in the '165 patent are used to treat inflammation-related disorders and that all the disorders claimed in the RE'048 patent are inflammation-related disorders.[63]

Because of this, the same reasoning applied by the Federal Circuit in previously rejecting the '068 patent as being invalid due to obviousness-type double patenting over the '165 patent would apply here as well. That is, because Pfizer admits that the RE'048 patent claims are not patentably distinct from the '165 patent, this Court should conclude that the claims of the RE'048 are not patentable due to obviousness-type double patenting over the '165 patent. *Pfizer*, 518 F.3d at 1363; *Geneva Pharms v. GlaxoSmithKline,* 349 F.3d 1373, 1385 (Fed. Cir. 2003); *Eli Lilly & Co. v. Barr Labs.*, 251 F.3d 955, 967 (Fed. Cir. 2001).

III. ARGUMENT: The RE'048 patent is also invalid if the Court finds that the claims are indefinite.

During the claim construction proceedings, Lupin and Apotex asserted that all of the claims of the RE'048 patent are indefinite. (Dkt Nos. 101-113, 135.) If the Court agrees, the claims are invalid as indefinite as a matter of law under 35 U.S.C. § 112, ¶ 2. *Honeywell Int'l, Inc. v. Int'l Trade Comm'n*, 341 F.3d 1332, 1338 (Fed. Cir. 2003); *Exxon Res. & Eng'g Co. v.*

[62] Sorenson Dec. Ex. 3 at RFA 2.
[63] Sorenson Dec. Ex. 3 at RFA 3-16.

United States, 265 F.3d 1371, 1375 (Fed. Cir. 2001). There would be no genuine issue as to any material fact and defendants would be "entitled to judgment as a matter of law." Fed. R. Civ. P. 56; *see also Biomedino, LLC v. Waters Techs. Corp.*, 490 F.3d 946, 949 (Fed. Cir. 2007); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1342 (Fed. Cir. 2003).

IV. CONCLUSION

Pfizer attempts to use the reissue process to cure its failure to file a divisional, something that the Federal Circuit forbids. Pfizer made certain choices during the prosecution of the '068 patent that allowed that patent to have a term of 18 months longer than other prior patents that shared the same parent application. But those same choices meant that those prior patents could be used to invalidate the '068 patent, which is exactly what happened when the Federal Circuit found Pfizer's '068 patent directed to methods of administering celecoxib invalid for claiming an obvious variation of the same invention in light of the related '165 patent directed to celecoxib.

In effect, the applications are like links in a chain. The reissue application and original '594 application are not the only links. There are many intervening links—the reissue application to the national stage '113 application to the PCT '720 application to the continuation-in-part '629 application to the original '594 application. These links mean that the RE'048 patent—like the '068 patent—did not and could not issue from a divisional of the original '594 application. Defendants respectfully request that this Court find the RE'048 patent did not issue from a divisional of the original '594 application and that the RE'048 patent is invalid as a matter of law. The RE'048 patent is invalid because its issuance violated the reissue statute. Further, for the same reason the Federal Circuit already found the '068 patent invalid for obviousness-type double patenting, the RE'048 patent is invalid as well.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 22nd day of November, 2013, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which will send a notification of such filing (NEF) to the following:

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